

USSN: 10/698,334
Group Art Unit: 3761
Docket No. 151-P-11699US01

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REMARKS

Claims 1 – 6 and 8 - 11 are pending in this application.

Claims 1 – 5 have been allowed.

Claims 6 and 8 – 11 have been rejected.

Allowable Subject Matter

Applicant appreciates the indication of allowable subject matter in the allowance of claims 1 – 5.

Rejections under 35 U.S.C. § 103

Claims 6 and 8 – 11 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,385,541 ("Kirsch et al '541") in view of U.S. Patent No. 5,156,592 ("Martin et al '592"). These rejections are respectfully traversed.

Kirsch et al '541 discloses a cerebrospinal fluid shunt ("CFS") with an elbow of approximately 90 degrees connecting a ventricle tube with a pump tube and a drain tube. See, for example, Figs. 1, 2, 3, 5, 7 and 8.

In Kirsch et al '541 claim 10, the elbow disclosed in the figures is said to form an obtuse angle with respect to the axes of both the ventricle and drain tubes, meaning that the bend will be anywhere from 90 degrees down to no bend at all, thereby forming an obtuse angle. Kirsch et al '541 states that "a typical CSF shunt is essentially L-shaped" so that the ventricle tube may be "inserted directly [emphasis added] into the skull so as to be in communication with the ventricular cavity," and then connected to the pump and drain tubes that runs "tangentially to the skull." (Kirsch et al '541, column 1, lines 61 – 68, column 2, lines 1 – 9) In other words, the typical CSF shunt is designed to run the ventricle tube straight into the ventricle, and the drain tube straight down the side of the skull to the neck, hence the "typical" 90 degree angle, which is the same form that Kirsch et al '541 discloses and describes. Kirsch et al '541 does not disclose or suggest any

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reason not to run the ventricle tube directly into the ventricle, thereby obviating any need for the elbow to have an angle much larger or smaller than 90 degrees.

In contrast, claim 6 requires an angle of approximately 180 degrees. The claimed shunt is specifically designed not to run the ventricle tube directly into the ventricle. As disclosed in paragraph [14], the catheter is designed to have a bend of up to 180 degrees "so that the distal end points generally in the upstream direction with respect to blood flow." This is to improve patient safety because, as noted in paragraph [12], "placing a distal catheter in the blood stream of the sagittal sinus creates the potential for blood clotting and resulting occlusion of the sinus passageway." Thus, the need to bend the shunt up to 180 degrees is an essential component of the invention, and the need for doing this was plainly not anticipated by Kirsch et al '541, which spoke specifically of inserting the shunt "directly" into the ventricle, and does not show, disclose or suggest a reason for inserting the shunt in any other way.

Thus, Kirsch et al '541 does not show, disclose, suggest or teach a shunt with an angle of more than 90 degrees, nor does Kirsch et al '541 suggest a reason for needing a shunt with an angle of more than 90 degrees. Kirsch et al '541 teaches away from the present invention by teaching an obtuse angle and teaching insertion of the end of the shunt directly into the ventricle.

The examiner contends that combining the elements of the CSF shunt disclosed in Kirsch et al '541 with Martin et al '592 renders claim 6 obvious. Martin et al '592 discloses a dual lumen catheter with a bend that forms an acute angle for use in a femoral vein. There is no disclosure in Martin et al '592 to suggest that the disclosed dual lumen catheter is suitable for use in the sagittal sinus.

There is no suggestion in Kirsch et al '541 to use a completely differently shaped shunt taken from a femoral vein catheter as disclosed in Martin et al '592. Nor is there any suggestion in Martin et al '592 that the disclosed femoral vein catheter is useful in the sagittal sinus. In short, there is nothing in either document that would suggest such a combination. And to make such a combination would go against the teaching in Kirsch

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et al '541 that both (1) the angle should be obtuse (Claim 10, line 35 – 36) and (2) the shunt is for direct, i.e., lumen first, insertion into the ventricle (Fig. 2).

It is respectfully submitted that the examiner is using hindsight reconstruction of the sort that the Court of Appeals for the Federal Circuit rejected in *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000). Without claim 6 in front of them, a person skilled in the art would not know to combine the elements of claim 6, thereby creating a shunt capable of being placed in the upstream direction with respect of the blood flow, thus improving the effectiveness of the shunt and the safety of the patient.

It is respectfully submitted that the rejection of claim 6 under 35 U.S.C. § 103(a) over Kirsch et al '541, in view of Martin et al '592, is improper and should be withdrawn.

Claims 8 – 11 are dependent on claim 6. As Kirsch et al '541, in view of Martin et al '592, fails to justify rejection of claim 6, they must also fail to justify rejection of claims 8 – 11.

Summary

In view of the amendments and arguments presented, claims 6 and 8 - 11 should be allowable. This application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully Submitted,

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